

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

KRKA  
PCT

KRKA, d.d., Novo mesto

WRITTEN OPINION

(PCT Rule 66)

To:

KRKA, D.D., NOVO MESTO  
Industrial Property Department,  
Smarjeska cesta 6  
8501 Novo mesto  
SLOVENIE

Date of mailing  
(day/month/year) 13/02/2004

Applicant's or agent's file reference  
KRKA2002/175

REPLY DUE  
within 2 / 00 months/days  
from the above date of mailing

International application No.

PCT/SI03/00024

International filing date (day/month/year)

14/07/2003

Priority date (day/month/year)

15/07/2002

International Patent Classification (IPC) or both national classification and IPC

A61K31/551

Applicant

KRKA, D.D., NOVO MESTO et al.

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.  
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 15/11/2004

Name and mailing address of the IPEA/



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Authorized officer

Examiner

Formalities officer  
(incl. extension of time limits)  
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**I. Basis of the opinion**

1. The basis of this written opinion is the application as originally filed.

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability**

1. In light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claims references).
2. If amendments are filed, the applicant should comply with the requirements of Rule 66.8 PCT and indicate the basis of the amendments in the documents of the application as originally filed (Article 34 (2) (b) PCT) otherwise these amendments may not be taken into consideration for the establishment of the international preliminary examination report. The attention of the applicant is drawn to the fact that if the application contains an unnecessary plurality of independent claims, no examination of any of the claims will be carried out.

NB: Should the applicant decide to request detailed substantive examination, then an international preliminary examination report will normally be established directly. Exceptionally the examiner may draw up a second written opinion, should this be explicitly requested.

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61K31/551 C07D495/04 A61P25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61K C07D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 01 47933 A (WAIN CHRISTOPHER PAUL ;HAMIED YUSUF KHWAJA (IN); RAO DHARMARAJ RAM) 5 July 2001 (2001-07-05) cited in the application examples	1-23
Y	EP 0 733 634 A (LILLY INDUSTRIES LTD ;LILLY CO ELI (US)) 25 September 1996 (1996-09-25) cited in the application page 2	1-23
Y	EP 0 733 635 A (LILLY INDUSTRIES LTD ;LILLY CO ELI (US)) 25 September 1996 (1996-09-25) cited in the application examples	1-23

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*B\* document member of the same patent family

Date of the actual completion of the international search

11 December 2003

Date of mailing of the international search report

19/12/2003

Name and mailing address of the ISA

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Authorized officer

Wolf, C

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 229 382 A (CHAKRABARTI JIBAN KUMAR ET AL) 20 July 1993 (1993-07-20) cited in the application example 2 -----	1-23